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Appln. No.	:	10/749,046	Confirmation No. 7407
Applicant	:	William J. Boyle et al.	
Filed	:	December 29, 2003	
Art Unit	:	3762	
Examiner	:	MacNeil, Elizabeth	
Title	:	EMBOLIC PROTECTION DEVICES	
Docket No.:	:	ACSES-66147 (G1738USC1)	
Customer No.	:	24201	September 15, 2008

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents

PRE-APPEAL BRIEF REQUEST FOR REVIEW

I. INTRODUCTION

The present invention relates to a filter element used to help in the loading and retrieval of embolic debris generated, for example, when a stenting procedure is being performed in an artery. The filter element includes a central region having an inlet opening and a storage reservoir for capturing the embolic debris. The central region includes a plurality of openings adapted to allow blood to flow therethrough but small enough to capture embolic debris larger than the size of the openings to contain the debris within the reservoir. The filter element includes a filter edge integral with a central region and also has an inlet opening. The claimed filter element is directed to the flexible membrane used to capture and collect embolic material entrained in body fluids. For this reason, all of the claims contain the recitation that the central region and filter edge are made from a filter membrane.

In use, the filter element is adapted to move from an expanded position to a collapsed position by sliding a restraining sheath initially over the filter edge and thereafter over the central region to move at least a portion of the filter element into the restraining sheath. The filter edge

is configured similar to a crown, with a pattern of alternation peaks and valleys that allow the filter to be incrementally introduced into the restraining sheath, thus preventing the material from entering the sheath all at once. As the filter element is being loaded or retrieved, the peaks of the filter edge would enter the restraining sheath first. Each valley region has a particular depth and each peak region has a particular height with at least two peak regions have different heights.

II. NOTICE OF APPEAL

A Notice of Appeal from the final Office Action dated May 15, 2008 and the Advisory Action of July 28, 2008 is being filed concurrently herewith along with the appropriate fee.

III. ISSUES ON APPEAL

At issue is whether claims 94-116 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,152,946 to Broome et al. (the "Broome patent") in view of U.S. Patent No. 5,800,457 to Gelbfish (the "Gelbfish patent"). A copy of the pending claims is attached hereto under Exhibit A. A copy of the drawings from the application is attached hereto as Exhibit B. A copy of the final Office Action dated May 15, 2008 is attached hereto as Exhibit C. The Broome patent is attached as Exhibit D. The Gelbfish patent is attached as Exhibit E.

IV. ARGUMENT

Claims 94-116 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent in view of the Gelbfish patent. Claims 94 to 113 are directed to the filter element which constitutes the filter membrane only. Claims 114-116 are directed to the combination of a frame assembly and a filter element made from the filter membrane.

The Examiner takes the position that the Gelbfish patent teaches an embolic filter with a sinusoidal configuration with valleys and peaks of different depths. Appellants strongly disagree with the Examiner characterization of the Gelbfish patent since this patent merely discloses a frame wire component 156 formed in a zig-zag pattern (Figure 10), not a filter element **made from a filter membrane** as recited in all of the pending claims. The presently defined invention is specifically directed to the membrane portion of the embolic protection device which has a plurality of openings adapted to allow blood to flow therethrough but to capture embolic debris larger than the size of the openings and contain the debris within a storage reservoir formed from the membrane. The membrane shown in the Gelbfish patent does not perform this function, but rather, simply acts as a **solid barrier** to direct blood flow and embolic material into a catheter

used to capture the embolic material. A single, large opening, adjacent to this continuous web or film 166 and membrane 172, is used in the Gelbfish patent to direct blood flow into a debris removal instrument that is used to draw fluid and collected material out of the patient utilizing suction. This single opening of the Gelbfish membrane does not capture embolic debris larger than the size of the opening and contain the debris within a storage reservoir formed from the membrane, as is recited in all of the claims. If the embolic material was larger than this single opening, then the debris removal device of Gelbfish would simply get clogged.

The web or film 166 and membrane 172 of the Gelbfish device lacks a plurality of perfusion openings. In fact, the Gelbfish patent actually teaches away from the use of perfusions openings in the web or film 166 and membrane 172 since the web or membrane is designed to enhance "the transmission of suction forces during a debris removal operation" (see column 11, lines 66-67 of the Gelbfish patent). Therefore, there are no perfusion openings in this "web or film 166" and "membrane 172" since this membrane must remain liquid impermeable in order to enhance the transmission of suction forces. Multiple openings in the Gelbfish membrane would inhibit the development of needed suction forces. Therefore, the use of a plurality of perfusion openings in the Gelbfish membrane would thwart the ability of the Gelbfish device to capture embolic material and create a suction that is needed to remove both the blood and embolic debris. Therefore, one skilled in the art would simply not look to the Gelbfish patent in solving the problems solved by the currently claimed invention since the Gelbfish membrane is used simply as a solid barrier to direct blood flow into another catheter that collects any embolic material entrained inn the blood. Accordingly, the Gelbfish patent fails to disclose the filter element of the present claimed invention.

The position taken by the Examiner, namely, that "Gelbfish teaches an embolic filter with an edge of a sinusoidal configuration with valleys and peaks of different depths" only relates to the wire frame that supports the "web or film 166" or "membrane 172." The web 166 and membrane 172 in the Gelbfish patent are all shown as components having a straight leading edge and lack a plurality of with openings. Figures 9 and 11 of the Gelbfish patent are reproduced below:

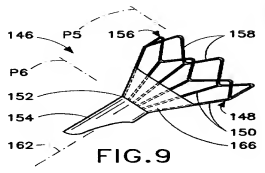

FIG.9

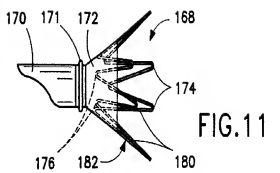

FIG.11

All of the webs or membranes disclosed in the Gelbfish patent have straight edges which are clearly shown in these figures above. Moreover, the Gelbfish does not teach that the web or membrane can be formed with the wire pattern shown in Figure 10. Rather, the Gelbfish patent states the following at column 11, lines 64-66:

> Filter body 148 is provided with a web or film 166 which renders the filter body liquid impermeable at least at its downstream side. Web or film 166 could be made long enough to cover or envelope prongs 150 and zig-zag element 156.

Therefore, the Gelbfish patent does not teach a filter membrane or web that has an edge configured in the shape shown in Figure 9. Rather, the web or membrane is simply extended upward with a linear edge as shown to cover the frame wire as is depicted in Figure 11 above.

Applicants submit that the Broome patent fails to disclose the structure of the pending claims as has been admitted by the Examiner in previous Office Actions. Appellant believes that the Examiner has simply used the claims as a roadmap in an attempt to find the various elements in unrelated prior art. The Gelbfish patent clearly fails to teach the use of a filter element made from a filter membrane that includes a filter edge having peaks and valleys of varying heights and depths. While it may use a wire edge in its support structure to avoid having the support frame enter into the coupling sleeve 154 at the same time, it is noted that the entire filter web 116 is drawn proximally into the coupling sleeve 154 at the same time. Figures 3A and 3D show how a rod or wire 42 is used to retract the support frame and filter web proximally into the tubular member or sleeve 26/154. Therefore, there is no need for a filter web having an edge with a sinusoidal pattern. Accordingly, the Gelbfish patent discloses only a filter web with a straight leading edge. The correct reading of the Gelbfish patent leads one to use only a straight edge filter membrane. Accordingly, the combination of the Broome patent with the Gelbfish patent would not result in the structure of the presently claimed invention.

Claim 115 requires each strut of the frame assembly to have a proximal end and a distal end, the proximal ends of the struts being attached to a proximal collar and the distal ends being attached to a distal collar. Applicants believe that this particular structure is not shown in the Broome patent or Gelbfish patent. The Examiner has taken the position that the element referred to as the mouth 28 of the frame 24 in the Broome patent constitutes a collar. Claim 116 requires each peak region of the filter element to be attached to a **strut** of the frame assembly. Claims 115 and 116 are directed to the embodiment disclosed in FIG. 41. Since the Examiner has taken the position that the mouth 28 constitutes one of the **collars**, the mouth 28 cannot constitute a strut of the frame assembly. The Broome patent clearly shows the filter element attached to the mouth 28 or collar, as the Examiner has interpreted the Broome patent. Therefore, the filter 22 of the Broome patent would not be considered attached to a strut of the frame assembly, as recited in claim 116, but rather, is attached to this "collar 28." The Examiner apparently has taken the position that the filter element is **indirectly** attached to the struts since the collar 28 is attached to the struts. However, Appellant believes that the Examiner's position is not a reasonable interpretation of the Broome patent. The Gelbfish patent also lacks the particular structure recited in claims 115 and 116. Accordingly, the combination of the Gelbfish patent with the Broome patent fails to disclose the particular structure recited in claim 116..

V. CONCLUSION

Appellant believes that the pending claims can be passed to issue as these claims were improperly rejected by the Examiner.

The Notice of Appeal filing fee of $510 and Pre-Appeal Brief filing fee of $510 are being paid by credit card with this electronic transmission. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

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